K112778

Premarket Notification [510(k)] Summary
Smart Segmentation Knowledge Based Contouring

DEC 2 9 2011

The following information is provided following the format of 21 CFR 807.92.

Submitter's Name:

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3100 Hansen Way E-110
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Contact Name: Vy Tran
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Date: September 2011

Proprietary Name:

Smart Segmentation - Knowledge Based Contouring

Classification Name:

Medical charged-particle radiation therapy system
21 CFR 892.5050, Class II
Product Code: 90 IYE

Common/Usual Name:

Smart Segmentation KBC

Predicate Device:

IKOEngelo™ Radiation Therapy Simulation System: (K083591)
Eclipse Treatment Planning System: (K071873)

Device Description:

Smart Segmentation - Knowledge Based Contouring is a software only product that provides a combined atlas and model based approach to automated segmentation of structures together with tools for manual contouring or editing of structures. A library of already contoured expert cases is provided which is searchable by anatomy, staging, or free text. Users also have the ability to add or modify expert cases to suit their clinical needs. Expert cases are registered to the target image and selected structures propagated. Smart Segmentation Knowledge Based Contouring supports inter and intra user consistency in contouring. This product also provides an anatomy atlas which gives examples of delineated organs for the whole upper body, as well as anatomy images and functional description for selectable structures. It is not used to simulate plans or calculate dose. The contouring information is exported to the treatment planning software device.

Statement of Intended Use

Smart Segmentation - Knowledge Based Contouring provides a combined atlas and model based approach for automated and manual segmentation of structures including target volumes and organs at risk to support the radiation therapy treatment planning process.

Statement of Indications for Use:

Smart Segmentation - Knowledge Based Contouring provides a combined atlas and model based approach for automated and manual segmentation of structures including target volumes and organs at risk to support the radiation therapy treatment planning process.

Technological Characteristics:

Refer to the Substantial Equivalence Comparison Chart

	Predicate Device IKOEngelo K083591	Predicate Device Eclipse with Smart Segmentation K071873	New Device Smart Segmentation - Knowledge Based Contouring
General Usage			
Support for External beam PHOTON planning	yes	yes	yes
Support for External beam PHOTON inverse planning	yes	yes	yes
Support for External beam ELECTRON planning	yes	yes	yes
Support for External beam PROTON planning	yes	yes	yes
Automated Structure Deliniation	yes	yes	yes
Graphical User Interface			
Three View Layout	yes	yes	yes
Four View Layout (ortho & 3d)	no	yes	yes
3d volume rendering	no	yes	yes
3d volume MIP rendering	no	yes	yes
3d volume MIP (rotating) rendering	no	yes	yes
3d mesh rendering	no	yes	yes
3d multiplane rendering single image	yes	yes	yes
3d multiplane rendering blended image	no	yes	yes
3d segments rendering	yes	yes	yes
Pixel Info Tool	yes	yes	yes
Distance Tool	yes	yes	yes
Pan Image	yes	yes	yes
Adjust window / level	yes	yes	yes
Angle Tool	yes	yes	yes
Area Profile Tool	no	yes	yes
Histogram Tool	yes	yes	yes
Select Structure Tool	yes	yes	yes
Planar Contour Drawing Tool	yes	yes	yes
Brush Tool	yes	yes	yes
Diffusion Brush Tool	no	yes	yes
Volumetric Contour Drawing Tool	no	yes	yes
Deform Structure Tool	no	no	yes
Image Threshold Tool	yes	yes	yes
PET Subvolume Threshold Tool	no	yes	yes
Boolean Structure Operations	yes	yes	yes

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Auto Match 3d (rigid)	yes	yes	yes
Manual Match (rigid)	yes	yes	yes
Automatic Deformable Registration	yes	no	yes
Region og interest selection	yes	yes	yes
Structure Editing			
Clear Structure	yes	yes	yes
Delete Structure	yes	yes	yes
Delete Structure Set	yes	yes	yes
Copy Structure to registered image	yes	yes	yes
Duplicate structure	yes	yes	yes
Set Structure Status	no	yes	yes
Change Structure ID	yes	yes	yes
Change Structure color & Style	yes	yes	yes
Show PET Patient Data	no	yes	yes
Structure Segmentation and Expert Case Selection			
Default to algorithm based segmentation for certain structures	no	yes (algorithm based is only option)	yes
Expert Case browser	yes	no*	yes
Expert case search - filters	yes	no*	yes
Expert case search - free text search	no	no*	yes
Expert case search - add / remove bookmarks	yes	no*	yes
Expert opinion text display	yes	no*	yes
Add new customer case to database	no	no*	yes
Modify existing expert case on database	no	no*	yes
Generate thumbnail preview for expert case	yes	no*	yes
Anatomy text book display	yes	no*	yes
Connectivity			
DICOM compatibility	yes	yes	yes

* Note: Eclipse with Smart Segmentation does not have an expert library for structure segmentation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

DEC 2 9 2011

Ms. Vy Tran
Vice President, Corporate Regulatory Affairs
Varian Medical Systems, Inc.
3100 Hansen Way E-110
PALO ALTO CA 94304

Re: K112778
Trade/Device Name: Smart Segmentation-Knowledge Based Contouring
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: December 13, 2011
Received: December 16, 2011

Dear Ms. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Smart Segmentation Knowledge Based Contouring

Indications for Use

510(k) Number (if known): K112778/S001

Device Name: Smart Segmentation - Knowledge Based Contouring

Indications for Use:

Smart Segmentation - Knowledge Based Contouring provides a combined atlas and model based approach for automated and manual segmentation of structures including target volumes and organs at risk to support the radiation therapy treatment planning process.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K112778/S001